App. of Ulrich et al.
Ser. No. 08/882,431

REMARKS

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43, 44, 47-49, 53, 56-58, 62 and 65-67 are pending. By the above amendments, we have amended claim 1 to clarify the invention, support for which is found throughout the original disclosure. We have also canceled non-elected claims 2, 3, 7-11, 15-17, 19-20, 24-28, 32-36, 40-42, 45, 46, 50-52, 54, 55, 59-61, 63, 64, 68-70 and 100-109 without prejudice or disclaimer.

We first note that it is unclear whether the Office Action dated April 25, 2001 is a final rejection. Page 1 states that it is not final, whereas page 3 states that it is final. We are proceeding on the assumption that the Office Action has final status.

In that Office Action, the Examiner has maintained two rejections. First, all the pending claims are rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention at the time the application was filed. Specifically, the Examiner has contended that the language in claim 1 referring to ". . . binding of the encoded altered toxin to either the MHC class II or multiple subsets of T cell antigen receptor is altered" is not supported by the specification. Basically, the Examiner has taken the position that Examples 4, 8 and 9 referring to SEA constructs are not applicable to the SEB constructs, ostensibly because it is unclear whether the SEB mutants also have the properties of the SEA mutants.

In our last response, we pointed out that the disclosure does indeed describe—with data—that the SEB mutants have the immunoprotective properties of the SEA mutants. It was found that residues at specific positions were conserved among bacterial superantigens, and our specification provides details how certain amino acid residues of SEA and SEB are likely to form part of integral molecular surfaces in contact with T-cell antigen receptors. (See pages 20 and 21)

This notwithstanding, in order to advance prosecution, we have amended independent claim 1 above to specify that the DNA fragment encoding Staphylococcal enterotoxin B has at least one amino acid of amino acid positions 43-53 of SEB and at

least one amino acid of amino acid positions 65-75, 87-97 and/or 103-113 of SEB altered such that binding of the encoded SEB to the MHC class II receptor and T cell antigen receptor is altered. Thus, this language is fully supported by the disclosure as originally filed, and withdrawal of this rejection is believed to be in order.

In the second rejection, claims 1, 18, 43, 44, 53 and 62 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Hayball et al. (International Immunology, 1994). The Examiner has reinstated this rejection on the grounds that the SEB mutant described by Hayball would inherently possess the properties of SEB Y61A. In the above amendments to independent claim 1, we believe we have distinguished our invention from anything taught or suggested by Hayball. Reconsideration is requested.

Having addressed all of the Examiner's concerns above, this application is believed to be in condition for allowance and notice of such is earnestly solicited.

If the Examiner has any questions or would like to make suggestions as to claim language, she is encouraged to contact Marlana K. Titus at (301) 924-9600.

Respectfully submitted,
By

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MARKED-UP VERSION OF AMENDED CLAIMS

1. (Thrice amended) An isolated and purified [Staphylococcal enterotoxin B] superantigen toxin DNA fragment encoding Staphylococcal enterotoxin B (SEB) in which at least one amino acid of amino acid positions 43-53 of SEB and at least one amino acid of amino acid positions 65-75, 87-97 and 103-113 of SEB have [which has] been altered such that binding of said encoded [altered toxin to either] SEB to the MHC class II [or multiple subsets of] receptor and T cell antigen receptor is altered.